Appointment

From: Witt, Mike (M) [MEWitt@dow.com]
Sent: 7/20/2017 6:44:33 PM
To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Accepted: Meeting w/ Dennis Deziel and Mike Witt from (DOW Chemical Company)
Location: DCRoomEast3156/DC-EPA-EAST-OCSPP

Start: 8/1/2017 7:30:00 PM
End: 8/1/2017 8:00:00 PM
Show Time As: Busy

Recurrence: (none)

From: Kime, Robin
Location: 3530 WJC North
Importance: Normal
Subject: Meeting with the Color Pigments Manufacturers Association
Start Date/Time: Wed 6/7/2017 5:00:00 PM
End Date/Time: Wed 6/7/2017 5:30:00 PM
CPMA 2015 Annual Report.pdf
CPMA 2016 Annual Report.pdf

Directions: Please use the William Jefferson Clinton North Entrance located on your right as you exit the Federal Triangle Metro Station. Please arrive 20 minutes prior to the meeting with photo IDs to clear Security.

EPA Contact: For an escort from Security to the meeting call **Ex. 6 - Personal Privacy** other matters call **Ex. 6 - Personal Privacy**

Attendees:

John Marten, President, Shepherd Color Company

Eric Christman, Vice President, Pigment Manufacturing NA, BASF Colors & Effects

Steve Camenisch, Product Stewardship, BASF Colors & Effects

Brooke DiDomenico, Technical Manager, Nation Ford Chemical

William Fetterly, Global Product Stewardship, BASF Colors & Effects

Frank Gillette, Site Manager, Flint Group Pigments

Dave Klebine, President, Apollo Colors

Ron Levi, President, Bruchsaler

Brian Marsicano, Managing Director, BASF Colors & Effects

Robert Mott, Global Regulatory Manger, Sun Chemical Corporation

Myron Petruch, President, Sun Chemical Corporation

Aram Terzian, Head of Dealer Management, EMD Performance Materials

Luiz Vieira, President, EMD Performance Materials

David Wawer, CPMA Executive Director

Glenn Merritt, CPMA Issues Counsel, Fitzpatrick & Merritt

Jamie Conrad, CPMA Agency Counsel, Conrad Law

Robert Helminiak, Managing Director, SOCMA Government Relations

Request: We understand that it would be most convenient to meet at the EPA HQ and are prepared to bring a group of our Board Members for a meeting. As confirmed by other industry colleagues, we believe that the most appropriate person to meet with would be Brittany, as she is an executive level political appointee that represents the policies of the new administration. The nature of the discussion is not meant to be technical, but rather focus on policies moving forward under the new EPA administrator. The discussion may also address EPA-related regulatory challenges:

1. The U.S. color pigment manufacturing industry, its downstream customers and its domestic economic impacts

2. Principal EPA-related regulatory challenges:

a. TSCA risk evaluations of Work Plan pigments, starting with Violet 29

b. Proper role of EPA regions in setting state water quality criteria — Region 10 override of WA DoE

Contact:

Tatiana Letcheva, Manager

Color Pigments Manufacturers Association, Inc.
1400 Crystal Drive, Suite 630

Arlington,VA 22202
(571) 348-5124

www.pigments.org

From: Deziel, Dennis (DR)
Location: DCRoomEast3156/DC-EPA-EAST-OCSPP
Importance: Normal
Subject: Accepted: Meeting w/ Dennis Deziel & Mike Witt (DOW Chemical Company)--alternative Testing
Start Date/Time: Tue 8/1/2017 7:30:00 PM
End Date/Time: Tue 8/1/2017 8:00:00 PM

Appointment

From: Cleland-Hamnett, Wendy [Cleland-Hamnett.Wendy@epa.gov]
Sent: 7/25/2017 1:27:49 AM
To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Tentative: Meeting w/ Dennis Deziel and Mike Witt from (DOW Chemical Company)
Location: DCRoomEast3156/DC-EPA-EAST-OCSPP

Start: 8/1/2017 7:30:00 PM
End: 8/1/2017 8:00:00 PM

Recurrence: (none)

Nancy, what's the topic of this one?

To: Beck, Nancy[Beck.Nancy@epa.gov]
From: HOPPER, SARA ELIZABETH
Sent: Thur 6/22/2017 8:45:03 PM
Subject: meeting re: TSCA Section 5

Hi Nancy. Just left you a voice mail. Would you have time to meet with my colleague, Lynn Dekleva, and me to discuss our recent experiences with the new chemicals program? Lynn will be in town next week and we would have some time Wed. afternoon the 28th. If that doesn't work on your end, could we look at the week of July 10th, or the following week if needed?

Thank you very much!

Sara

Sara Hopper

Manager, Federal Government Affairs

DuPont Government Affairs

601 Pennsylvania Avenue NW

Suite 325, North Building

Washington, DC 20004

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acceptance of a contract offer. This e-mail does not constitute a consent to the use of sender's contact information for direct marketing purposes or for transfers of data to third parties.

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Ex. 6 - Personal Privacy

To: Beck, Nancy[Beck.Nancy@epa.gov]
Cc: Ethan Mathews[mathews@dc.ncga.com]
From: James McVaney
Sent: Wed 7/19/2017 5:34:26 PM
Subject: Row crop farm tour - Corn

Nancy, when we first spoke you mentioned that you would like to tour a row crop farm. I have cc'd Ethan Mathews of the National Corn Growers Association. You will be with him tomorrow at the Pesticide Policy Coalition meeting, which he co-chairs. NCGA would be able to organize a tour for you and other Agency staff that would be informative and show the use of FIFRA regulated products in that setting.

I'll leave it to Ethan to follow up but wanted to "set the table."

Best,

Jim

Jim McVaney

Senior Director, Federal Affairs & Policy

Bayer: Science For A Better Life

Bayer Corporation

Bayer Corp-CGR-USGR

801 Pennsylvania Avenue, NW

Suite 745

Washington, DC 20004 US

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From: Microsoft Outlook
Location: DCRoomEast3156/DC-EPA-EAST-OCSPP
Importance: Normal
Subject: Meeting Forward Notification: Meeting w/ Dennis Deziel & Mike Witt (DOW Chemical Company)--alternative Testing
Start Date/Time: Tue 8/1/2017 7:30:00 PM
End Date/Time: Tue 8/1/2017 8:00:00 PM

Your meeting was forwarded

Pierce, Alison has forwarded your meeting request to additional recipients.

Meeting

Meeting w/ Dennis Deziel & Mike Witt (DOW Chemical Company)--alternative Testing

Meeting Time

Tuesday, August 1, 2017 3:30 PM-4:00 PM.

Recipients

Scarano, Louis

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Sent by Microsoft Exchange Server

To: Beck, Nancy[Beck.Nancy@epa.gov]
Cc: Marshall, Venus[Marshall.Venus@epa.gov]; DEKLEVA, LYNN ANN[Lynn-Ann.Dekleva-1@dupont.com]
From: HOPPER, SARA ELIZABETH
Sent: Fri 6/23/2017 8:22:13 PM
Subject: RE: meeting re: TSCA Section 5

Thanks very much Nancy and Venus! We have a time on your calendar on July 10th. Venus, I forwarded the invite to my colleague Lynn Dekleva, copied above, so you should get a response from her too. Nancy, Lynn and I thought it might make sense for Jeff Morris to join us, if you agree. Re: specific topics, Lynn should probably weigh in, but at a high level, the need for transparency and more open communication is one area of concern for us, and a tendency towards overly precautionary approaches and actions (vs. the risk-based approach mandated by LCSA) is another. I hope that is helpful. If more background would be helpful, I can work with Lynn to get that to you.

Thanks again to both you and Venus for responding so quickly and helping us to get this set up.

Have a great weekend!

Sara

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Thursday, June 22, 2017 6:21 PM
To: HOPPER, SARA ELIZABETH <Sara.E.Hopper@dupont.com>
Cc: Marshall, Venus <Marshall.Venus@epa.gov>
Subject: [EXTERNAL] RE: meeting re: TSCA Section 5

Hi Sarah,

Next week is pretty crazy but I think we can find 30 min the week of July 10. Venus, can you please help us find a window?

If there is a specific topic within the new chemicals program and you would like some of our

leadership team to join me please let me know.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

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beck.nancy@epa.gov

From: HOPPER, SARA ELIZABETH [mailto:Sara.E.Hopper@dupont.com]
Sent: Thursday, June 22, 2017 4:45 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: meeting re: TSCA Section 5

Hi Nancy. Just left you a voice mail. Would you have time to meet with my colleague, Lynn Dekleva, and me to discuss our recent experiences with the new chemicals program? Lynn will be in town next week and we would have some time Wed. afternoon the 28th. If that doesn't work on your end, could we look at the week of July 10th, or the following week if needed?

Thank you very much!

Sara

Sara Hopper

Manager, Federal Government Affairs

DuPont Government Affairs

601 Pennsylvania Avenue NW

Suite 325, North Building

Washington, DC 20004

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sara.e.hopper@dupont.com

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http://www.DuPont.com/corp/email_disclaimer.html

To: Beck, Nancy[Beck.Nancy@epa.gov]
From: James McVaney
Sent: Fri 6/23/2017 6:03:19 PM
Subject: ACC Alum and Meeting follow up

Nancy,

This is to follow up on a meeting you had last week with a group from CropLife, and to connect on specific issues. I have sent an LinkedIn request to connect, noting that I am also an ACC Alum, having run the energy and climate team in the early 2000s. I currently run all of Bayer's advocacy for our CropScience business.

I am hoping we can get coffee next week to talk shop and follow up on the meeting you had with the group from CropLife last week. We were not able to be present but have a number of things cooking right now. Please let me know if you have availability.

Best,

Jim

Jim McVaney

Senior Director, Federal Affairs & Policy

---

801 Pennsylvania Avenue, NW

Suite 745

Washington, DC 20004 US

Ex. 6 - Personal Privacy

E-mail: james.mcvaney@bayer.com

Web: http://www.bayer.com

To: Beck, Nancy[Beck.Nancy@epa.gov]; Marshall, Venus[Marshall.Venus@epa.gov]
Cc: Witt, Mike (M)[MEWitt@dow.com]
From: Deziel, Dennis (DR)
Sent: Wed 7/19/2017 2:01:48 PM
Subject: RE: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Venus,

We can be available on August 1 at either 11am or anytime 3:30pm or later. 30 minutes would be great. Thank you!

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Tuesday, July 18, 2017 5:44 PM
To: Deziel, Dennis (DR) <DRDeziel@dow.com>
Cc: Marshall, Venus <Marshall.Venus@epa.gov>
Subject: RE: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Dennis—

I'm happy to meet with Mike Witt and can invite our leads for the development of our alternatives strategy.

Please work with Venus to find a 30 minute window that will work.

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

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beck.nancy@epa.gov

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]
Sent: Tuesday, July 18, 2017 1:18 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Nancy,

Dow is a leader in non-animal testing methods, including extensive, collaborative work with EPA's National Center for Computational Toxicology. We want to engage on this issue in as helpful way as possible. One of our leaders on this issue, Mike Witt, head of our toxicology center, will be in town August 1st. Would you be available to meet when he is here to discuss this issue? Or we could meet with others as you recommend.

Thank you, Dennis

Dennis Deziel Government Affairs

The Dow Chemical Company

500 North Capitol Street, NW Suite 200

Washington DC 20001

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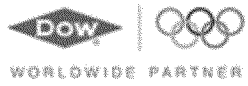
E-Mail: DRDeziel@dow.com



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Bloomberg News

Chemical Makers Urge EPA to Accept Non-Animal Safety Data

By Pat Rizzuto

Chemical manufacturers want the EPA to be more receptive than they say the European Chemicals Agency has been in accepting chemical safety data derived from non-animal tests.

"We've had challenges in the EU getting many of these alternatives accepted. We hope the U.S. will be a more friendly place," Athena Keene, a senior toxicologist at Afton Chemical Corp., said at a recent science policy meeting.

Afton, a subsidiary of the NewMarket Corp., which makes fuel and lubricant additives, has registered chemicals under the EU's registration, evaluation, authorization and restriction of chemicals, or REACH, law. REACH encourages the use of non-animal tests, yet animal welfare groups and chemical manufacturers have appealed many decisions in which the European Chemicals Agency rejected non-animal data the companies sought to submit.

The Environmental Protection Agency soon will invite chemical manufacturers, trade associations, animal welfare advocates, and academic and other scientists to help shape an agency strategy to develop and use the results from non-animal, or "alternative," tests for chemical decision making, said Tala Henry, who directs the risk assessment division of the EPA's Office of Pollution Prevention and Toxics. Keene and Henry were among the speakers at a July 12 Toxicology Forum meeting that discussed the Lautenberg Chemical Safety Act, which amended the Toxic Substances Control Act in 2016.

TSCA's amendments require the EPA to develop a non-animal testing strategy by June 22, 2018, to promote the development and use of new scientifically valid test methods that don't use mammals or other vertebrates. That strategy is part a broader requirement for EPA to reduce and replace the use of animals at a time when more tests may be required.

The EPA is deciding whether to seek public participation through a workshop, releasing a draft concept document, or some other method, Henry said. The agency expects to invite interested parties to provide input in a few months, she said.

Reducing Liability

Harvey Clewell, a senior scientist at ScitoVation, a research institute specializing in cell-based and computational methods as chemical evaluation methods, echoed Keene's point that some European chemical regulators have not used available non-animal test methods.

The U.S., however, has a growing academic, federal and industry scientific infrastructure supporting their development and use, he said. Clewell pointed to federal agencies such the EPA and National Institute of Environmental Health Sciences (NIEHS), which have been developing and using a spectrum of automated chemical testing systems.

Using alternative tests "just makes good sense," especially in the early stages of a new chemical's development, Clewell said. "There's a lot of liability potential for chemicals. They can cost a company a lot of money once they are out there. Wouldn't it behoove a company to run some quick tests and say 'this has red flags why should we pursue it'."

Suzanne Hartigan, director of science policy and regulatory affairs at the International Fragrance Association North America, said fragrance makers already have developed strategies to obtain chemical safety data from alternative tests, so they could comply with the EU's Cosmetics Products Regulation and its predecessor—the Cosmetics Directive—which phased out the use of animal tests on cosmetics and their ingredients.

The Research Institute for Fragrance Materials, Inc., which assesses fragrance safety, has developed a phased in, or "tiered," testing strategy that begins with evaluating existing data for a particular fragrance, proceeds to examining information about similar compounds, and builds toward in vitro and computer-modeled tests, Hartigan said. After such alternative data sources have been utilized, animal tests can be considered, she said, urging EPA to consider some of these strategies.

No Double Standard

Henry said EPA already would review non-animal chemical safety data if companies submitted it but added, "It's not flooding into us."

The more companies submit alternative data, the more it will help the agency understand their uses and limitations, she said.

Richard Denison, lead senior scientist with the Environmental Defense Fund, said that group supports the use of alternative tests. Details about tests used to generate data submitted to the EPA should, however, be made available to build public confidence in the tests' predictions, he said. Protocols used for statutorily required animal tests are publicly available.

Many of the assays the EPA uses for its automated chemical testing program, called ToxCast, and that the NIEHS uses for a similar program called Tox21, are proprietary, Denison said.

Alternative test advocates also should avoid a double standard, Denison said.

There's a tendency for proponents to want to use data from an alternative test if it suggests a chemical would not raise health or environmental concerns, he said. Yet if such tests show a problem, then the proponents argue the tests aren't valid because they don't reflect the "real world," Denison said.

To: Beck, Nancy[Beck.Nancy@epa.gov]
Cc: Marshall, Venus[Marshall.Venus@epa.gov]
From: James McVaney
Sent: Thur 7/6/2017 3:05:50 PM
Subject: Re: ACC Alum and Meeting follow up

Dr Beck,

I am a bit early and at the reception desk.

Thanks,

Jim

Jim McVaney

Senior Director, Federal Affairs & Policy

_____

Bayer: Science For A Better Life

Bayer Corporation

Bayer Corp-CGR-USGR

801 Pennsylvania Avenue, NW

Suite 745

Washington, DC 20004 US

Ex. 6 - Personal Privacy

E-mail: james.mcvaney@bayer.com

Web: http://www.bayer.com

On Jun 23, 2017, at 5:54 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

Hi Jim,

Nice to "meet" you. My calendar is pretty crazy packed next week. Why don't we try for a 30 minute window after the July 4th holiday.

Venus, can you help us find a window?

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: James McVaney [mailto:james.mcvaney@bayer.com]
Sent: Friday, June 23, 2017 2:03 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: ACC Alum and Meeting follow up

Nancy,

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our CropScience business.

I am hoping we can get coffee next week to talk shop and follow up on the meeting you had with the group from CropLife last week. We were not able to be present but have a number of things cooking right now. Please let me know if you have availability.

Best,

Jim

Jim McVaney

Senior Director, Federal Affairs & Policy

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Washington, DC 20004 US

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E-mail: james.mcvaney@bayer.com

Web: http://www.bayer.com

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To: Beck, Nancy[Beck.Nancy@epa.gov]
From: Deziel, Dennis (DR)
Sent: Tue 7/18/2017 5:18:18 PM
Subject: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Nancy,

Dow is a leader in non-animal testing methods, including extensive, collaborative work with EPA's National Center for Computational Toxicology. We want to engage on this issue in as helpful way as possible. One of our leaders on this issue, Mike Witt, head of our toxicology center, will be in town August 1st. Would you be available to meet when he is here to discuss this issue? Or we could meet with others as you recommend.

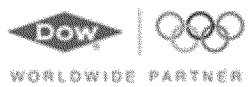
Thank you, Dennis

Dennis Deziel Government Affairs

The Dow Chemical Company

500 North Capitol Street, NW Suite 200

Washington DC 20001
Ex. 6 - Personal Privacy
E-Mail: DRDeziel@dow.com



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Bloomberg News

Chemical Makers Urge EPA to Accept Non-Animal Safety Data

By Pat Rizzuto

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Afton, a subsidiary of the NewMarket Corp., which makes fuel and lubricant additives, has registered chemicals under the EU's registration, evaluation, authorization and restriction of chemicals, or REACH, law. REACH encourages the use of non-animal tests, yet animal welfare groups and chemical manufacturers have appealed many decisions in which the European Chemicals Agency rejected non-animal data the companies sought to submit.

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TSCA's amendments require the EPA to develop a non-animal testing strategy by June 22, 2018, to promote the development and use of new scientifically valid test methods that don't use mammals or other vertebrates. That strategy is part a broader requirement for EPA to reduce and replace the use of animals at a time when more tests may be required.

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developed a phased in, or "tiered," testing strategy that begins with evaluating existing data for a particular fragrance, proceeds to examining information about similar compounds, and builds toward in vitro and computer-modeled tests, Hartigan said. After such alternative data sources have been utilized, animal tests can be considered, she said, urging EPA to consider some of these strategies.

No Double Standard

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The more companies submit alternative data, the more it will help the agency understand their uses and limitations, she said.

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Many of the assays the EPA uses for its automated chemical testing program, called ToxCast, and that the NIEHS uses for a similar program called Tox21, are proprietary, Denison said.

Alternative test advocates also should avoid a double standard, Denison said.

There's a tendency for proponents to want to use data from an alternative test if it suggests a chemical would not raise health or environmental concerns, he said. Yet if such tests show a problem, then the proponents argue the tests aren't valid because they don't reflect the "real world," Denison said.

To: Beck, Nancy[Beck.Nancy@epa.gov]
From: Goldstein, Bernard D
Sent: Wed 5/31/2017 7:12:06 PM
Subject: RE: Follow-up on SRA Session

Hi Nancy

Most recent version of proposal is below. The five speakers for 10 min each in alphabetical order are Arvai, Beck, Denison, Goldstein and White. I need to get this in by **tonight**

Also – would you like to be listed with a middle initial?

Thanks again for doing this

Bernie

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Monday, May 22, 2017 6:49 PM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Subject: RE: Follow-up on SRA Session

Got it. When you have a final abstract send it my way and I'll take a look.

It is a bit awkward.. I think I can be on a panel with them, but do not want to be collaborating with them, or even seen as collaborating with them.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
Sent: Monday, May 22, 2017 3:52 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Follow-up on SRA Session

Sorry to be unclear. I do need names for the submission, but do not need your participation in the preparation of the abstract. I apologize, as I should have realized that this might be a problem for you

Needless to say, you could withdraw at any time.

Bernie

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Monday, May 22, 2017 7:42 AM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Subject: RE: Follow-up on SRA Session

Bernie,

As I am recused from interactions with ACC, it's a bit awkward for me to be planning a session with them.

As you said you don't need names just yet for the submission, why don't you just move ahead

without me and lets circle back in the fall to see if it makes sense for me to join the panel.

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
Sent: Monday, May 22, 2017 5:24 AM
To: White, Kimberly <Kimberly_White@americanchemistry.com>
Cc: Rick_Becker@americanchemistry.com; Joe Arvai <jlarvai@umich.edu>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Follow-up on SRA Session

Hi Kimberly

Your changes are OK with me, but I have added a few words ("and decreasing the likelihood of the involvement of knowledgeable academic scientists in EPA review processes") to reflect the substantial concern of the academic community about the following provision in the SAB Act. (I also think that the provision is short-sighted from an industry perspective).

"(H) a Board member shall have no current grants or contracts from the Environmental Protection Agency

and shall not apply for a grant or contract for 3 years following the end of that member's service on the Board."

There is also other language in the Act which could be interpreted as the above provision being applicable to not only full SAB Board membership, but to the members of any EPA review process of any hazard or risk assessment

Let me know if the new language is acceptable to you. I'm also copying Joe Arvai and Nancy Beck in case they want to respond, either in writing or by phone, particularly as there is now no description of Administrator Pruitt's goals or activities in this area. While not necessary, we do have room in the abstract for additional language

Bernie

Bernard D. Goldstein, MD

Professor Emeritus and Dean Emeritus

University of Pittsburgh Graduate School of Public Health

130 Desoto St; Rm A-710

Pittsburgh PA 15261

Ex. 6 - Personal Privacy

From: White, Kimberly [mailto:Kimberly_White@americanchemistry.com]
Sent: Friday, May 19, 2017 6:22 PM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Cc: Becker, Rick <Rick_Becker@americanchemistry.com>
Subject: RE: Follow-up on SRA Session

Dear Bernie:

Thanks for the additional information about the session and the abstract. We offer some suggestions to the abstract attached. The suggestions attempt to focus the abstract on the discussion regarding what are appropriate approaches for optimal provision of scientific advice to regulatory agencies and work to adjust some of the language that may be perceived as inflammatory.

Kind Regards,

Kimberly

Kimberly Wise White, Ph.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

Kimberly_White@americanchemistry.com

700 2nd Street NE | Washington, DC | 20002

Ex. 6 - Personal Privacy

www.americanchemistry.com

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
Sent: Friday, May 19, 2017 2:53 PM
To: White, Kimberly

Cc: Becker, Rick
Subject: RE: Follow-up on SRA Session

Dear Dr White

Great news!!

My previous email to you is below; along with the original attachment of the preliminary draft

Bernie

Bernard D. Goldstein, MD

Emeritus Professor and Emeritus Dean

Graduate School of Public Health

University of Pittsburgh

Rm A710 Crabtree Hall

130 De Soto St

Pittsburgh, PA 15261

Ex. 6 - Personal Privacy

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involvement in a proposal for a Roundtable to be submitted to the Society for Risk Analysis for its annual meeting in Crystal City next December 10-13.

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Ex. 6 - Personal Privacy

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Subject: Re: SRA panel

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Sent from my iPhone

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Regards,
Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
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To: Beck, Nancy <Beck.Nancy@epa.gov>
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Best regards

Bernie

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Emeritus Professor and Emeritus Dean

Graduate School of Public Health

University of Pittsburgh

Rm A710 Crabtree Hall

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Pittsburgh, PA 15261

Ex. 6 - Personal Privacy

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I will have to find out if I have to run this through a clearance process—not sure how that works yet and if those procedures apply to me.

Thanks,
Nancy

****

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

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Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council

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++++++++++++++++++++++++++++ This message may contain confidential information and is intended only for the individual named. If you are not the named addressee do not disseminate, distribute or copy this email. Please notify the sender immediately by email if you have received this email by mistake and delete this email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

To: Cleland-Hamnett, Wendy[Cleland-Hamnett.Wendy@epa.gov]
Cc: Beck, Nancy[Beck.Nancy@epa.gov]; Jakob, Avivah[Jakob.Avivah@epa.gov]
From: Dunton, Cheryl
Sent: Wed 6/14/2017 8:57:45 PM
Subject: RE: Press Inquiry from Bloomberg on Glyphosate

Great thanks. Will send to OPA.

From: Cleland-Hamnett, Wendy
Sent: Wednesday, June 14, 2017 4:57 PM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: Re: Press Inquiry from Bloomberg on Glyphosate

Ok with me

Wendy Cleland-Hamnett

Acting Assistant Administrator

Principal Deputy Assistant Administrator

Office of Chemical Safety & Pollution Prevention

U.S. EPA

On Jun 14, 2017, at 3:32 PM, Dunton, Cheryl <Dunton.Cheryl@epa.gov> wrote:

See incoming below from Bloomberg on glyphosate and our response in red. Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process Let me know if you have comments/edits before this goes to OPA. Thanks.

Incoming:

From Michael Byhoff, Producer - Bloomberg

Ex. 6 - Personal Privacy

I am a producer for Bloomberg news and I'm working on a video about Monsanto, and more specifically, the impact of glyphosate on farming.

It is a video from the objective viewpoint of "what would the world look like if we stopped using glyphosate" The piece is about how glyphosate has changed the world of farming, and what life would be like if it was found out to be carcinogenic.

For example, how would a farmer's life change, what would happen to produce prices in the grocery store, and what the alternatives (if any) is in place to replace glyphosate.

I want to get the EPA's point of view from the studies brought forth by the IARC that glyphosate could "potentially" be carcinogenic, and see where the government stands from the scientific studies that appear to make the argument on both sides of the argument

Response:

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

Begin forwarded message:

From: "Michael Byhoff (BLOOMBERG/ NEWSROOM:)" <mbyhoff@bloomberg.net>
Date: May 19, 2017 at 2:02:51 PM EDT
To: <Jones.Enesta@epa.gov>
Subject: Re:EPA Inquiry
Reply-To: Michael Byhoff <mbyhoff@bloomberg.net>

The piece is about how glyphosate has changed the world of farming, and what life would be like if it was found out to be carcinogenic.

For example, how would a farmer's life change, what would happen to produce prices in the grocery store, and what the alternatives (if any) is in place to replace glyphosate.

I want to get the EPA's point of view from the studies brought forth by the IARC that glyphosate could "potentially" be carcinogenic, and see where the government stands from the scientific studies that appear to make the argument on both sides of the argument.

My deadline is early June.

Thanks,

Michael Byhoff

Producer - Bloomberg

Ex. 6 - Personal Privacy

From: Jones.Enesta@epa.gov

Subject: Re:EPA Inquiry

Hi Michael,

I am reaching out RE: your request below. Can you tell me more about your piece, what exactly you are seeking from EPA and your deadline, please?

From: Michael Byhoff (BLOOMBERG/ NEWSROOM:) [mailto:mbyhoff@bloomberg.net]
Sent: Thursday, May 18, 2017 5:01 PM
To: Mears, Mary <Mears.Mary@epa.gov>
Subject: Bloomberg news requesting an interview about Glyphosate

Hi Mary,

I am a producer for Bloomberg news and I'm working on a video about Monsanto, and more specifically, the impact of glyphosate on farming.

It is a video from the objective viewpoint of "what would the world look like if we stopped using glyphosate" and was hoping to interview an expert in the area.

I can give you a call to further discuss as well. Let me know if you're available!

Best,

Michael Byhoff

Producer - Bloomberg

Ex. 6 - Personal Privacy

Enesta Jones

U.S. EPA

Office of Media Relations

Ex. 6 - Personal Privacy

"The root of all joy is gratefulness."

To: Goldstein, Bernard D[bdgold@pitt.edu]
From: Beck, Nancy
Sent: Wed 5/31/2017 8:47:59 PM
Subject: RE: Follow-up on SRA Session

Bernie,

I'm not seeing the proposal.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
Sent: Wednesday, May 31, 2017 3:12 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Follow-up on SRA Session

Hi Nancy

Most recent version of proposal is below. The five speakers for 10 min each in alphabetical order are Arvai, Beck, Denison, Goldstein and White. I need to get this in by **tonight**

Also – would you like to be listed with a middle initial?

Thanks again for doing this

Bernie

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Monday, May 22, 2017 6:49 PM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Subject: RE: Follow-up on SRA Session

Got it. When you have a final abstract send it my way and I'll take a look.

It is a bit awkward.. I think I can be on a panel with them, but do not want to be collaborating with them, or even seen as collaborating with them.

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Sorry to be unclear. I do need names for the submission, but do not need your participation in the preparation of the abstract. I apologize, as I should have realized that this might be a problem for you

Needless to say, you could withdraw at any time.

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From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
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Ex. 6 - Personal Privacy

Personal Matters / Ex. 6

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Cc: Rick_Becker@americanchemistry.com; Joe Arvai <jlarvai@umich.edu>; Beck, Nancy <Beck.Nancy@epa.gov>
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Professor Emeritus and Dean Emeritus

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130 Desoto St; Rm A-710

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Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

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To: HOPPER, SARA ELIZABETH[Sara.E.Hopper@dupont.com]
Cc: Marshall, Venus[Marshall.Venus@epa.gov]
From: Beck, Nancy
Sent: Thur 6/22/2017 10:21:09 PM
Subject: RE: meeting re: TSCA Section 5

Hi Sarah,

Next week is pretty crazy but I think we can find 30 min the week of July 10. Venus, can you please help us find a window?

If there is a specific topic within the new chemicals program and you would like some of our leadership team to join me please let me know.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: HOPPER, SARA ELIZABETH [mailto:Sara.E.Hopper@dupont.com]
Sent: Thursday, June 22, 2017 4:45 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: meeting re: TSCA Section 5

Hi Nancy. Just left you a voice mail. Would you have time to meet with my colleague, Lynn Dekleva, and me to discuss our recent experiences with the new chemicals program? Lynn will

be in town next week and we would have some time Wed. afternoon the 28th. If that doesn't work on your end, could we look at the week of July 10th, or the following week if needed?

Thank you very much!

Sara

Sara Hopper

Manager, Federal Government Affairs

DuPont Government Affairs

601 Pennsylvania Avenue NW

Suite 325, North Building

Washington, DC 20004

Ex. 6 - Personal Privacy

sara.e.hopper@dupont.com

http://www.DuPont.com/corp/email_disclaimer.html

To: HOPPER, SARA ELIZABETH[Sara.E.Hopper@dupont.com]
Cc: Marshall, Venus[Marshall.Venus@epa.gov]
From: Beck, Nancy
Sent: Mon 7/24/2017 9:50:54 PM
Subject: RE: meeting to discuss ESA/FIFRA

Hi Sara,

Lets try for 30 minutes the week of the August 18th.

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: HOPPER, SARA ELIZABETH [mailto:Sara.E.Hopper@dupont.com]
Sent: Monday, July 24, 2017 2:04 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Marshall, Venus <Marshall.Venus@epa.gov>
Subject: meeting to discuss ESA/FIFRA

Hi Nancy, I wanted to see if there was a time in August when you and I could discuss the ESA/FIFRA issue. I have some travel early in the month, but around from the 9th through Sept. 1. Happy to look at September too if that works better on your end.

Thanks!

Sara

Sara Hopper

Manager, Federal Government Affairs

DuPont Government Affairs

601 Pennsylvania Avenue NW

Suite 325, North Building

Washington, DC 20004

Ex. 6 - Personal Privacy

sara.e.hopper@dupont.com

To: Goldstein, Bernard D[bdgold@pitt.edu]
From: Beck, Nancy
Sent: Mon 5/22/2017 10:48:35 PM
Subject: RE: Follow-up on SRA Session

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Bernie

Bernard D. Goldstein, MD

Professor Emeritus and Dean Emeritus

University of Pittsburgh Graduate School of Public Health

130 Desoto St; Rm A-710

Pittsburgh PA 15261

Ex. 6 - Personal Privacy

From: White, Kimberly [mailto:Kimberly_White@americanchemistry.com]
Sent: Friday, May 19, 2017 6:22 PM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Cc: Becker, Rick <Rick_Becker@americanchemistry.com>
Subject: RE: Follow-up on SRA Session

Dear Bernie:

Thanks for the additional information about the session and the abstract. We offer some suggestions to the abstract attached. The suggestions attempt to focus the abstract on the discussion regarding what are appropriate approaches for optimal provision of scientific advice to regulatory agencies and work to adjust some of the language that may be perceived as inflammatory.

Kind Regards,

Kimberly

Kimberly Wise White, Ph.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

Kimberly_White@americanchemistry.com

700 2nd Street NE | Washington, DC | 20002

Ex. 6 - Personal Privacy

www.americanchemistry.com

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
Sent: Friday, May 19, 2017 2:53 PM
To: White, Kimberly
Cc: Becker, Rick
Subject: RE: Follow-up on SRA Session

Dear Dr White

Great news!!

My previous email to you is below; along with the original attachment of the preliminary draft

Bernie

Bernard D. Goldstein, MD

Emeritus Professor and Emeritus Dean

Graduate School of Public Health

University of Pittsburgh

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Ex. 6 - Personal Privacy

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There are some time constraints in getting this completed, particularly as I will be at Dow Chemical for much of next week, so hope both that you can do this and that you can respond by midweek

Many thanks for your consideration

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Subject: Re: SRA panel

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Sent from my iPhone

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Bernie,

I think the framing of the abstract is a bit biased and needs some work.

I cant and wont speak for ACC at all, but for this topic, I direct you to Kimberly White. She has testified in front of congress on these issues. Kimberly_White@americanchemistry.com.

If I have more time this week I will noodle the abstract but it's a bit of a busy time here.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

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beck.nancy@epa.gov

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
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To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: SRA panel

Hi Nancy

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Attached is what I've written so far, and some of the directions from the SRA web site. I'm about to run out for most of the rest of the afternoon. I'd like to get this out of the way as soon as reasonably possible as am at meetings at Dow most of next week.

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I'm envisioning the 3 or 4 panelists for the Roundtable would have about 15 min each for presentation and the rest of the 90 minutes would be for a facilitated discussion led by the moderator

I'm thinking of asking Granger Morgan or Terry Yosie to be the moderator, but your suggestion for moderator or for another panelist who supports the ACC position on the SAB Act would be very much appreciated.

Best regards

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Subject: SRA panel

Hi Bernie,

Got your message and am happy to consider the request. Can you send me all the information on the proposal (abstract, goals, participants, etc)?

I will have to find out if I have to run this through a clearance process—not sure how that works yet and if those procedures apply to me.

Thanks,
Nancy

****

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

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Sent: Friday, May 19, 2017 2:35 PM
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Subject: Follow-up on SRA Session

Dear Dr. Goldstein:

Thank you for your voicemail earlier today. I have had an opportunity to follow-up with Rick (cc'd on this email) and I understand you have a commitment from EPA to participate. Given the confirmation of EPA's participation, we will also confirm ACC's participation. Could you send me the proposed abstract or session description? Also it would be helpful to know of any additional information you need from ACC for the session and any deadlines.

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To: Goldstein, Bernard D[bdgold@pitt.edu]
From: Beck, Nancy
Sent: Mon 5/22/2017 11:42:20 AM
Subject: RE: Follow-up on SRA Session

Bernie,

As I am recused from interactions with ACC, it's a bit awkward for me to be planning a session with them.

As you said you don't need names just yet for the submission, why don't you just move ahead without me and lets circle back in the fall to see if it makes sense for me to join the panel.

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

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beck.nancy@epa.gov

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
Sent: Monday, May 22, 2017 5:24 AM
To: White, Kimberly <Kimberly_White@americanchemistry.com>
Cc: Rick_Becker@americanchemistry.com; Joe Arvai <jlarvai@umich.edu>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Follow-up on SRA Session

Hi Kimberly

Your changes are OK with me, but I have added a few words ("and decreasing the likelihood of the involvement of knowledgeable academic scientists in EPA review processes") to reflect the substantial concern of the academic community about the following provision in the SAB Act. (I also think that the provision is short-sighted from an industry perspective).

"(H) a Board member shall have no current grants or contracts from the Environmental Protection Agency

and shall not apply for a grant or contract for 3 years following the end of that member's service on the Board."

There is also other language in the Act which could be interpreted as the above provision being applicable to not only full SAB Board membership, but to the members of any EPA review process of any hazard or risk assessment

Let me know if the new language is acceptable to you. I'm also copying Joe Arvai and Nancy Beck in case they want to respond, either in writing or by phone, particularly as there is now no description of Administrator Pruitt's goals or activities in this area. While not necessary, we do have room in the abstract for additional language

Bernie

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To: James McVaney[james.mcvaney@bayer.com]
Cc: Ethan Mathews[mathews@dc.ncga.com]
From: Beck, Nancy
Sent: Wed 7/19/2017 7:54:48 PM
Subject: RE: Row crop farm tour - Corn

Thanks Jim! I look forward to meeting Ethan tomorrow.

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: James McVaney [mailto:james.mcvaney@bayer.com]
Sent: Wednesday, July 19, 2017 1:34 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Ethan Mathews <mathews@dc.ncga.com>
Subject: Row crop farm tour - Corn

Nancy, when we first spoke you mentioned that you would like to tour a row crop farm. I have cc'd Ethan Mathews of the National Corn Growers Association. You will be with him tomorrow at the Pesticide Policy Coalition meeting, which he co-chairs. NCGA would be able to organize a tour for you and other Agency staff that would be informative and show the use of FIFRA regulated products in that setting.

I'll leave it to Ethan to follow up but wanted to "set the table."

Best,

Jim

Jim McVaney

Senior Director, Federal Affairs & Policy

Bayer: Science For A Better Life

Bayer Corporation

Bayer Corp-CGR-USGR

801 Pennsylvania Avenue, NW

Suite 745

Washington, DC 20004 US

Ex. 6 - Personal Privacy

E-mail: james.mcvaney@bayer.com

Web: http://www.bayer.com

directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.

To: James McVaney[james.mcvaney@bayer.com]
Cc: Marshall, Venus[Marshall.Venus@epa.gov]
From: Beck, Nancy
Sent: Fri 6/23/2017 9:54:12 PM
Subject: RE: ACC Alum and Meeting follow up

Hi Jim,

Nice to "meet" you. My calendar is pretty crazy packed next week. Why don't we try for a 30 minute window after the July 4th holiday.

Venus, can you help us find a window?

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

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beck.nancy@epa.gov

From: James McVaney [mailto:james.mcvaney@bayer.com]
Sent: Friday, June 23, 2017 2:03 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: ACC Alum and Meeting follow up

Nancy,

This is to follow up on a meeting you had last week with a group from CropLife, and to connect on specific issues. I have sent an LinkedIn request to connect, noting that I am also an ACC Alum, having run the energy and climate team in the early 2000s. I currently run all of Bayer's advocacy for our CropScience business.

I am hoping we can get coffee next week to talk shop and follow up on the meeting you had with the group from CropLife last week. We were not able to be present but have a number of things cooking right now. Please let me know if you have availability.

Best,

Jim

Jim McVaney

Senior Director, Federal Affairs & Policy

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801 Pennsylvania Avenue, NW

Suite 745

Washington, DC 20004 US

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E-mail: james.mcvaney@bayer.com

Web: http://www.bayer.com

To: Schmit, Ryan[schmit.ryan@epa.gov]; Jakob, Avivah[Jakob.Avivah@epa.gov]
From: Beck, Nancy
Sent: Tue 7/25/2017 1:21:46 PM
Subject: Fwd: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
Ex. 6 - Personal Privacy
Beck.Nancy@epa.gov

Begin forwarded message:

From: "Deziel, Dennis (DR)" <DRDeziel@dow.com>
Date: July 18, 2017 at 1:18:18 PM EDT
To: "Beck, Nancy" <Beck.Nancy@epa.gov>
Subject: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Nancy,

Dow is a leader in non-animal testing methods, including extensive, collaborative work with EPA's National Center for Computational Toxicology. We want to engage on this issue in as helpful way as possible. One of our leaders on this issue, Mike Witt, head of our toxicology center, will be in town August 1st. Would you be available to meet when he is here to discuss this issue? Or we could meet with others as you recommend.

Thank you, Dennis

Dennis Deziel Government Affairs

The Dow Chemical Company

500 North Capitol Street, NW Suite 200

Washington DC 20001
Ex. 6 - Personal Privacy
E-Mail: DRDeziel@dow.com

--

Bloomberg News

Chemical Makers Urge EPA to Accept Non-Animal Safety Data

By Pat Rizzuto

Chemical manufacturers want the EPA to be more receptive than they say the European Chemicals Agency has been in accepting chemical safety data derived from non-animal tests.

"We've had challenges in the EU getting many of these alternatives accepted. We hope the U.S. will be a more friendly place," Athena Keene, a senior toxicologist at Afton Chemical Corp., said at a recent science policy meeting.

Afton, a subsidiary of the NewMarket Corp., which makes fuel and lubricant additives, has registered chemicals under the EU's registration, evaluation, authorization and restriction of chemicals, or REACH, law. REACH encourages the use of non-animal tests, yet animal welfare groups and chemical manufacturers have appealed many decisions in which the European Chemicals Agency rejected non-animal data the companies sought to submit.

The Environmental Protection Agency soon will invite chemical manufacturers, trade associations, animal welfare advocates, and academic and other scientists to help shape an agency strategy to develop and use the results from non-animal, or "alternative," tests for chemical decision making, said Tala Henry, who directs the risk assessment division of the EPA's Office of Pollution Prevention and Toxics. Keene and Henry were among the speakers at a July 12 Toxicology Forum meeting that discussed the Lautenberg Chemical Safety Act, which amended the Toxic Substances Control Act in 2016.

TSCA's amendments require the EPA to develop a non-animal testing strategy by June 22, 2018, to promote the development and use of new scientifically valid test methods that don't use mammals or other vertebrates. That strategy is part a broader requirement for EPA to reduce and replace the use of animals at a time when more tests may be required.

The EPA is deciding whether to seek public participation through a workshop, releasing a draft concept document, or some other method, Henry said. The agency expects to invite interested parties to provide input in a few months, she said.

Reducing Liability

Harvey Clewell, a senior scientist at ScitoVation, a research institute specializing in cell-based and computational methods as chemical evaluation methods, echoed Keene's point

that some European chemical regulators have not used available non-animal test methods.

The U.S., however, has a growing academic, federal and industry scientific infrastructure supporting their development and use, he said. Clewell pointed to federal agencies such the EPA and National Institute of Environmental Health Sciences (NIEHS), which have been developing and using a spectrum of automated chemical testing systems.

Using alternative tests "just makes good sense," especially in the early stages of a new chemical's development, Clewell said. "There's a lot of liability potential for chemicals. They can cost a company a lot of money once they are out there. Wouldn't it behoove a company to run some quick tests and say 'this has red flags why should we pursue it'."

Suzanne Hartigan, director of science policy and regulatory affairs at the International Fragrance Association North America, said fragrance makers already have developed strategies to obtain chemical safety data from alternative tests, so they could comply with the EU's Cosmetics Products Regulation and its predecessor—the Cosmetics Directive—which phased out the use of animal tests on cosmetics and their ingredients.

The Research Institute for Fragrance Materials, Inc., which assesses fragrance safety, has developed a phased in, or "tiered," testing strategy that begins with evaluating existing data for a particular fragrance, proceeds to examining information about similar compounds, and builds toward in vitro and computer-modeled tests, Hartigan said. After such alternative data sources have been utilized, animal tests can be considered, she said, urging EPA to consider some of these strategies.

No Double Standard

Henry said EPA already would review non-animal chemical safety data if companies submitted it but added, "It's not flooding into us."

The more companies submit alternative data, the more it will help the agency understand their uses and limitations, she said.

Richard Denison, lead senior scientist with the Environmental Defense Fund, said that group supports the use of alternative tests. Details about tests used to generate data submitted to the EPA should, however, be made available to build public confidence in the tests' predictions, he said. Protocols used for statutorily required animal tests are publicly available.

Many of the assays the EPA uses for its automated chemical testing program, called ToxCast, and that the NIEHS uses for a similar program called Tox21, are proprietary, Denison said.

Alternative test advocates also should avoid a double standard, Denison said.

There's a tendency for proponents to want to use data from an alternative test if it suggests a chemical would not raise health or environmental concerns, he said. Yet if such tests show a problem, then the proponents argue the tests aren't valid because they don't reflect the "real world," Denison said.

To: Marshall, Venus[Marshall.Venus@epa.gov]
From: Beck, Nancy
Sent: Fri 6/23/2017 8:37:03 PM
Subject: FW: meeting re: TSCA Section 5

I'm fine with adding Jeff.

Thanks!

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

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beck.nancy@epa.gov

From: HOPPER, SARA ELIZABETH [mailto:Sara.E.Hopper@dupont.com]
Sent: Friday, June 23, 2017 4:22 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Marshall, Venus <Marshall.Venus@epa.gov>; DEKLEVA, LYNN ANN <Lynn-Ann.Dekleva-1@dupont.com>
Subject: RE: meeting re: TSCA Section 5

Thanks very much Nancy and Venus! We have a time on your calendar on July 10th. Venus, I forwarded the invite to my colleague Lynn Dekleva, copied above, so you should get a response from her too. Nancy, Lynn and I thought it might make sense for Jeff Morris to join us, if you agree. Re: specific topics, Lynn should probably weigh in, but at a high level, the need for transparency and more open communication is one area of concern for us, and a tendency towards overly precautionary approaches and actions (vs. the risk-based approach mandated by LCSA) is another. I hope that is helpful. If more background would be helpful, I can work with Lynn to get that to you.

Thanks again to both you and Venus for responding so quickly and helping us to get this set up.

Have a great weekend!

Sara

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Thursday, June 22, 2017 6:21 PM
To: HOPPER, SARA ELIZABETH <Sara.E.Hopper@dupont.com>
Cc: Marshall, Venus <Marshall.Venus@epa.gov>
Subject: [EXTERNAL] RE: meeting re: TSCA Section 5

Hi Sarah,

Next week is pretty crazy but I think we can find 30 min the week of July 10. Venus, can you please help us find a window?

If there is a specific topic within the new chemicals program and you would like some of our leadership team to join me please let me know.

Regards,
Nancy

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To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: meeting re: TSCA Section 5

Hi Nancy. Just left you a voice mail. Would you have time to meet with my colleague, Lynn Dekleva, and me to discuss our recent experiences with the new chemicals program? Lynn will be in town next week and we would have some time Wed. afternoon the 28th. If that doesn't work on your end, could we look at the week of July 10th, or the following week if needed?

Thank you very much!

Sara

Sara Hopper

Manager, Federal Government Affairs

DuPont Government Affairs

601 Pennsylvania Avenue NW

Suite 325, North Building

Washington, DC 20004

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sara.e.hopper@dupont.com

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

http://www.DuPont.com/corp/email_disclaimer.html

To: Cleland-Hamnett, Wendy[Cleland-Hamnett.Wendy@epa.gov]
From: Beck, Nancy
Sent: Tue 7/25/2017 11:23:24 AM
Subject: Fwd: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

FYI. Dow wants to talk about alternative testing.

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
Ex. 6 - Personal Privacy
Beck.Nancy@epa.gov

Begin forwarded message:

From: "Deziel, Dennis (DR)" <DRDeziel@dow.com>
Date: July 18, 2017 at 1:18:18 PM EDT
To: "Beck, Nancy" <Beck.Nancy@epa.gov>
Subject: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Nancy,

Dow is a leader in non-animal testing methods, including extensive, collaborative work with EPA's National Center for Computational Toxicology. We want to engage on this issue in as helpful way as possible. One of our leaders on this issue, Mike Witt, head of our toxicology center, will be in town August 1st. Would you be available to meet when he is here to discuss this issue? Or we could meet with others as you recommend.

Thank you, Dennis

Dennis Deziel Government Affairs

The Dow Chemical Company

500 North Capitol Street, NW Suite 200

Washington DC 20001

Ex. 6 - Personal Privacy

E-Mail: DRDeziel@dow.com

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Bloomberg News

Chemical Makers Urge EPA to Accept Non-Animal Safety Data

By Pat Rizzuto

Chemical manufacturers want the EPA to be more receptive than they say the European Chemicals Agency has been in accepting chemical safety data derived from non-animal tests.

"We've had challenges in the EU getting many of these alternatives accepted. We hope the U.S. will be a more friendly place," Athena Keene, a senior toxicologist at Afton Chemical Corp., said at a recent science policy meeting.

Afton, a subsidiary of the NewMarket Corp., which makes fuel and lubricant additives, has registered chemicals under the EU's registration, evaluation, authorization and restriction of chemicals, or REACH, law. REACH encourages the use of non-animal tests, yet animal welfare groups and chemical manufacturers have appealed many decisions in which the European Chemicals Agency rejected non-animal data the companies sought to submit.

The Environmental Protection Agency soon will invite chemical manufacturers, trade associations, animal welfare advocates, and academic and other scientists to help shape an agency strategy to develop and use the results from non-animal, or "alternative," tests for chemical decision making, said Tala Henry, who directs the risk assessment division of the EPA's Office of Pollution Prevention and Toxics. Keene and Henry were among the speakers at a July 12 Toxicology Forum meeting that discussed the Lautenberg Chemical Safety Act, which amended the Toxic Substances Control Act in 2016.

TSCA's amendments require the EPA to develop a non-animal testing strategy by June 22, 2018, to promote the development and use of new scientifically valid test methods that don't use mammals or other vertebrates. That strategy is part a broader requirement for EPA to reduce and replace the use of animals at a time when more tests may be required.

The EPA is deciding whether to seek public participation through a workshop, releasing a draft concept document, or some other method, Henry said. The agency expects to invite interested parties to provide input in a few months, she said.

Reducing Liability

Harvey Clewell, a senior scientist at ScitoVation, a research institute specializing in cell-

based and computational methods as chemical evaluation methods, echoed Keene's point that some European chemical regulators have not used available non-animal test methods.

The U.S., however, has a growing academic, federal and industry scientific infrastructure supporting their development and use, he said. Clewell pointed to federal agencies such the EPA and National Institute of Environmental Health Sciences (NIEHS), which have been developing and using a spectrum of automated chemical testing systems.

Using alternative tests "just makes good sense," especially in the early stages of a new chemical's development, Clewell said. "There's a lot of liability potential for chemicals. They can cost a company a lot of money once they are out there. Wouldn't it behoove a company to run some quick tests and say 'this has red flags why should we pursue it'."

Suzanne Hartigan, director of science policy and regulatory affairs at the International Fragrance Association North America, said fragrance makers already have developed strategies to obtain chemical safety data from alternative tests, so they could comply with the EU's Cosmetics Products Regulation and its predecessor—the Cosmetics Directive—which phased out the use of animal tests on cosmetics and their ingredients.

The Research Institute for Fragrance Materials, Inc., which assesses fragrance safety, has developed a phased in, or "tiered," testing strategy that begins with evaluating existing data for a particular fragrance, proceeds to examining information about similar compounds, and builds toward in vitro and computer-modeled tests, Hartigan said. After such alternative data sources have been utilized, animal tests can be considered, she said, urging EPA to consider some of these strategies.

No Double Standard

Henry said EPA already would review non-animal chemical safety data if companies submitted it but added, "It's not flooding into us."

The more companies submit alternative data, the more it will help the agency understand their uses and limitations, she said.

Richard Denison, lead senior scientist with the Environmental Defense Fund, said that group supports the use of alternative tests. Details about tests used to generate data submitted to the EPA should, however, be made available to build public confidence in the tests' predictions, he said. Protocols used for statutorily required animal tests are publicly available.

Many of the assays the EPA uses for its automated chemical testing program, called ToxCast, and that the NIEHS uses for a similar program called Tox21, are proprietary, Denison said.

Alternative test advocates also should avoid a double standard, Denison said.

There's a tendency for proponents to want to use data from an alternative test if it suggests a chemical would not raise health or environmental concerns, he said. Yet if such tests show a problem, then the proponents argue the tests aren't valid because they don't reflect the "real world," Denison said.

To: Milhouse, Gloria[Milhouse.Gloria@epa.gov]
From: Beck, Nancy
Sent: Wed 7/19/2017 2:04:47 PM
Subject: Fwd: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
Ex. 6 - Personal Privacy
Beck.Nancy@epa.gov

Begin forwarded message:

From: "Deziel, Dennis (DR)" <DRDeziel@dow.com>
Date: July 19, 2017 at 10:01:48 AM EDT
To: "Beck, Nancy" <Beck.Nancy@epa.gov>, "Marshall, Venus" <Marshall.Venus@epa.gov>
Cc: "Witt, Mike (M)" <MEWitt@dow.com>
Subject: RE: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Venus,

We can be available on August 1 at either 11am or anytime 3:30pm or later. 30 minutes would be great. Thank you!

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Tuesday, July 18, 2017 5:44 PM
To: Deziel, Dennis (DR) <DRDeziel@dow.com>
Cc: Marshall, Venus <Marshall.Venus@epa.gov>
Subject: RE: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Dennis—

I'm happy to meet with Mike Witt and can invite our leads for the development of our alternatives strategy.

Please work with Venus to find a 30 minute window that will work.

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

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beck.nancy@epa.gov

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]
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Cc: Venus Marshall (Marshall.Venus@epa.gov)[Marshall.Venus@epa.gov]
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beck.nancy@epa.gov

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